

May 25, 2000

MEMORANDUM

SUBJECT: **Propargite**; Chemical No. 097601. HED's Responses to Uniroyal's Comments on HED's Preliminary Human Health Risk Assessment for Propargite, Case # 0243. DP Barcode: D266002.

From: Thurston G. Morton, Risk Assessor
Reregistration Branch 4
Health Effects Division (7509C)

Thru: Susan V. Hummel, Branch Senior Scientist
Reregistration Branch 4
Health Effects Division (7509C)

To: Jacqueline McQueen/Robert McNally
Special Review Branch
Special Review and Reregistration Division (7508W)

This memo addresses the HED related comments contained in the April 27, 2000 letter from Uniroyal Chemical Company, Inc. representing the comments on the propargite Reregistration Eligibility Decision (RED).

The rebuttal letter from Uniroyal contained comments addressing the propargite risk assessment and the documents used to prepare the risk assessment. This memorandum will serve to respond to only those documents prepared by HED. Responses to comments were answered by members of the HED propargite risk assessment team of Thurston Morton, Suhair Shallal, Jerry Stokes, Seyed Tadayon, and Jerome Blondell/Monica Spann. Bolded page numbers cited are page numbers from Uniroyal's submission for the registrant comment period.

Uniroyal's Comment:

Page 5: 1) Dietary Exposure and Risk: The Agency's values for chronic national and regional dietary exposure and risk are overestimates. Methodologies used in cattle dietary burden calculations, and values for tea residues and grape juice and tea percent crop treated are not correct. When these factors are corrected, the recalculated risks are similar to Uniroyal's negligible risk estimates of 1.01×10^{-6} (national) and 1.2×10^{-6} (regional). It should be noted that drinking water exposure is included in these risk numbers.

HED's Response: HED has conducted a revised dietary exposure analysis incorporating some of Uniroyal's comments. New dietary burdens were calculated and used in the calculation of animal tissue residues. A new memorandum on the dietary exposure analysis will be forthcoming. The correct processing factor for grape juice is 0.19 not 0.022. The 0.022x processing factor was for unfermented juice.

Uniroyal's Comment:

Page 5: 2) Q_1^* : Uniroyal believes there are two errors in the Agency's determination:

The revised Agency Q_1^* of 2.01×10^{-1} is in part based upon exclusion of animals that died before the first tumor. Exclusion of animals that died before the observation of the first tumor is inappropriate in a time-to-tumor model.

An expected lifespan of 130 weeks, the default value, was used. The proper lifespan to use is 105 weeks.

HED's Response: This issue has been addressed by HED in a previous memorandum (S. Shallal, 1/4/2000, D259592).

Uniroyal's Comment:

Page 6: 4) Acute Dietary Endpoint for Females 13-50: We disagree with the Agency's rationale for requiring an acute dietary risk assessment, which is based on the finding of an increase in fused sternebrae at a dose of 10 mg/kg/day in the rabbit developmental study. Our view is based on the following: the presence of maternal toxicity; i.e., reduction in body weight, at this dose, the lack of a dose response for this effect, the significance of this effect, which should be classified as a developmental variant and not a malformation, and finally, the fact that a decrease in maternal body weight in female workers will not occur from a single exposure to propargite.

HED's Response: This issue has been addressed by HED in a previous memorandum (S. Shallal, 1/4/2000, D259592).

Uniroyal's Comment:

Page 6: 5) Post-application Exposure: Several errors, detailed under specific comments, were made in determining revised reentry periods for certain crop uses. We have indicated below the uses where these mistakes occurred. In addition, at the proper phase in the RED process, Uniroyal will propose alternative mitigation measures for uses such as hops where a markedly longer REI would constitute a *de facto* cancellation.

CITRUS: There should be a more inclusive use of DFR data and a lower maximum use rate;

GRAPES: Because cane turning is the highest contact activity, a lower TC should be used to assess "all other activities;"

TREE NUTS: The higher REI should apply to activities other than shaker harvest;

MINT: Reentry for this crop should not be assessed in parallel with hops.

HED's Response: Citrus: Exposure was calculated for a range of application rates with a maximum application rate of 4.5 lb ai/acre based on the label for SLN CA860070. Exposures were below HED's level of concern even at 4.5 lb ai/acre.

Grapes: The use of a lower transfer coefficient will need the concurrence of the HED Exposure SAC.

Tree Nuts: The use of a lower transfer coefficient will need the concurrence of the HED Exposure SAC.

Mint: HED will separate mint and hops and calculate separate exposures for the two crops.

Uniroyal's Comment:

HED Toxicology Chapter (9/9/99)

Page 7: Table 1: Toxicity Profile for Propargite Technical

page 2 - It is stated in this table that the requirement for the rat developmental toxicity study (870.3700) has not been satisfied. We believe that this is a misprint since Uniroyal Chemical Company has submitted a study, MRID# 41346501, that has been reviewed by the agency and found to be acceptable.

HED's Response: Table 1 of the HED Toxicology Chapter has been revised to read that the requirement for the rat developmental toxicity study has been satisfied.

Uniroyal's Comment:

Page 7: Table 1: Toxicity Profile for Propargite Technical

page 3 – The “No” in Table 1 under Guideline No. 870.7485 should be changed to a “Yes.” The table in the Jan. 25, 1999 review of toxicity studies, Table 1, page 5, reviews each study by MRID number and concludes that the three studies represented by MRID numbers 413863302, 41712101, and 41813202 are all acceptable and as a package make an acceptable 870.7485 guideline study. Some of the other studies shown in table 1 were not acceptable but the guideline is fulfilled and the “No” entry in table 1 is thus misleading.

HED's Response: Table 1 of the HED Toxicology Chapter has been revised to read that the metabolism requirement has been satisfied.

Uniroyal's Comment:

Page 7: Table 1: Toxicity Profile for Propargite Technical

page 6 – 2nd paragraph, line 2. Epoxidized soybean oil (ESO) was not the vehicle in this experiment. This was a dietary study with no “vehicle.” The Omite technical contained a small amount of ESO as a stabilizer.

HED's Response: The text in the HED Toxicology Chapter referenced to in this comment has been revised to read: “Omite (89.87 % ai) was administered to 2 groups of 60 male Charles River CD rats in epoxidized soybean oil (used as a stabilizer) at dose....”

Uniroyal's Comment:

Page 7: Table 1: Toxicity Profile for Propargite Technical

page 11 – Table 3. The value for the Q_1^* is not the same as the revised value in the text in other parts of the RED.

HED's Response: Table 3 of the HED Toxicology Chapter has been revised to reflect the new Q_1^* value in accordance with the memorandum by L. Brunsman (11/23/99, Doc. # 013867).

Uniroyal's Comment:

Page 9: Occupational Exposure and Risk Assessment

page 5 - The maximum application is 4.5 lb ai/acre.

HED's Response: The maximum single application rate is 4.5 lb ai/acre. This typographical error will be corrected.

Uniroyal's Comment:

Page 9: Occupational Exposure and Risk Assessment

page 5 - Propargite is not registered for use in forestry or forest planting. The conclusions of short- and intermediate-term assessments should not reference MOEs for scenarios associated with such uses.

HED's Response: Uniroyal is correct regarding no forest uses being registered. This error will be corrected in the revised risk assessment document.

Uniroyal's Comment:

Page 9: Occupational Exposure and Risk Assessment

page 6 - postapplication exposure - Current propargite labels do not allow reentry in 48 hours without PPE including coveralls and chemical-resistant gloves, headgear, and footwear. The REIs addressed by the OREB assessments currently range from 3 days (strawberries) to 42 days (turning cane in table grapes). Establishment of longer Federal REIs for propargite to substantially reflect those originally set by CDPR has already taken place. These REIs have been found to be adequately protective in California, and post-application exposure incidents outside of California, including in hops, are virtually non-existent.

HED's Response: Actual data was used in the calculation of the REIs. Some of the REIs are several days longer than the CDPR REIs.

Uniroyal's Comment:

Page 9: 3.0 Hazard Characterization

page 9 - As noted in our comments on the HIARC determination on propargite toxicity, we do not agree with the rationale for the acute dietary endpoint.

HED's Response: This issue has been addressed by HED in a previous memorandum (S. Shallal, 1/4/2000, D259592).

Uniroyal's Comment:

Page 9: 3.0 Hazard Characterization

page 9 - As noted in our comments in the quantitative risk assessment, the Q_1^* from the time-to-tumor model is 0.171. It appears that the EPA value of 0.201 was obtained from excluding animals that died before observation of the first tumor. This exclusion is not appropriate in time-to-tumor models. Because there is no statistical difference in survival between controls and treated males in the rat chronic study, the Multistage quantal model would also be appropriate to use. The Q_1^* from the Multistage quantal model is 0.033.

HED's Response: This issue has been addressed by HED in a previous memorandum and a full explanation of HED's policies for calculating Q_1^* values is included (S. Shallal, 1/4/2000, D259592).

Uniroyal's Comment:

Page 9: 4.0 Exposure Assessment

4.1 Summary of Registered Uses

page 12 - SLNs

There are several mistakes in the list of current SLNs for propargite products. These mistakes are:

Listed as current but previously canceled: CO95001 (for Comite II).

Uniroyal SLNs not listed (but 1999 maintenance fee paid): WI990016 and WA910016 (for Comite).

Third party SLN not listed (but 1999 maintenance fee paid by Uniroyal): CA860070.

Third party SLNs not listed (1999 maintenance fees presumably paid by third party): CA920011, OR940006 and WA940007.

HED's Response: The reference to SLN CO950001 will be removed from Table 2 of the HED Risk Assessment. Uniroyal states that HED failed to list CA940008, OR910009, WA910017,

CA860070, and AZ000006. These are non-food uses so therefore would not be included in Table 2 which includes only feed/food uses of propargite. Uniroyal states that CA920011 was not listed in the table, but this SLN is listed. The two SLNs for mint IN990002 and WI990016 will be included in the updated table.

Uniroyal's Comment:

Page 10: 4.0 Exposure Assessment

4.1 Summary of Registered Uses

page 12 - Section 3 Labels

For Section 3 labels, the following errors were noted:

Maximum reentry interval is 60 days, not 56 (sorghum grain – Comite and Comite II)

Last approved labels for Omite-30W and Omite-30WS are dated 1/14/98

HED's Response: HED assumes that Uniroyal intended to specify the maximum preharvest interval is 60 days, not 56 for sorghum grain. The preharvest interval for propargite ranges from 7 to 60 days. This error will be corrected in the Revised Risk Assessment. PPLS lists the latest approved labels for Omite-30W (EPA Reg. No. 400-82) and Omite-30WS (EPA Reg. No. 400-427) as 7/9/99. Table 2 in the Risk Assessment will be corrected to include the latest label approval date as 7/9/99 for these two products.

Uniroyal's Comment:

Page 10: 4.0 Exposure Assessment

4.2 Food Exposure

page 13 - On October 1, 1996, Uniroyal requested label changes to correct errors in the crop rotation statement. The draft RED corrects two of these errors by: (1) extending the statement to all formulated product labels (not just Comite) and (2) removing the specification for cotton or corn as the target crops. However, there was another change requested on 10/1/96 which has not been addressed. That change is the following specification:

an interval of 6 months for rotated root crops and
an interval of 2 months for all other rotated crops except root crops

The specified small grain rotation of 82 days would not change. The rationale (still valid) for this change is as follows:

The 6-month interval for rotated crops, other than small grains and leafy

vegetables, causes hardship for certain growers.

EPA requires three representative crops be tested to determine the crop rotation intervals. For propargite, those crops and the EPA interim determinations were:

leafy vegetables – 2 month
root crops – 6 months
small grains – 82 days

Uniroyal does not disagree with those findings, rather with the way the labels are currently worded and the recommendation supporting that wording under 4.2 on pg. 15.

HED's Response: A memorandum pertaining to rotational crops is under review (D230867). A decision will be forthcoming.

Uniroyal's Comment:

Page 11: 4.0 Exposure Assessment

4.2 Food Exposure

page 14 – end of first paragraph – “Additional confirmatory data for radiovalidation of analytical methods are required.” Our records show submittal of radiovalidation studies on the following matrices:.....

HED's Response: HED has responded to this comment previously (J. Stokes, 5/3/2000, D255691). No additional data are required for the enforcement methodology. The Revised Risk Assessment document will be revised to reflect this.

Uniroyal's Comment:

Page 12: 4.2.3 - 4.2.6 Acute and Chronic Dietary Exposure Reassessment

page 16 - Uniroyal has just recently submitted acute and chronic dietary exposure analyses for propargite. These analyses utilized PDP monitoring data, field trial data, calculated livestock anticipated residues, percent crop treated, and drinking water monitoring data. In the acute dietary analysis (MRID No. 45051501), exposure to females (13 years and older) was estimated as 0.000677 mg/kg bw/day at the 99.9th percentile. This was 0.85% of the acute population adjusted dose, with a margin of exposure of >11,000.

Although EPA calculated the chronic cancer risk values using the Agency's revised Q₁* value of 0.201, and not the Q₁* value of 0.171, the main difference between the EPA and the Uniroyal assessments is the exposure to beef and milk products.

This difference, based on EPA's calculation of livestock dietary burdens, appears to be due to:

including almond hulls in both national and regional beef cattle diets (as almond hulls are fed almost exclusively to dairy cattle, they would not be included in beef cattle diets);

exclusion of percent crop treated for livestock feed items (in chronic exposure estimates, percent crop treated would be considered for livestock feed items)

extrapolation of residues from feeding studies to anticipated dietary burdens based on an averaging basis, and not a linear regression basis (linear regression gives a more appropriate concentration-dependent anticipated livestock dietary burden).

cattle dietary makeup did not follow the commonly used and accepted roughage estimates of 50% (beef cattle) and 70% (dairy cattle).

HED's Response: HED has conducted a revised dietary exposure analysis incorporating some of Uniroyal's comments. New dietary burdens were calculated and used in the calculation of animal tissue residues. The Revised Risk Assessment document will be corrected to reflect this. A memorandum pertaining to the new dietary exposure analysis will be forthcoming. Uniroyal's submitted dietary exposure assessment will be responded to in a separate document.

Uniroyal's Comment:

Page 13: 4.3 - Non-Dietary Exposure

**4.3.1.1 Occupational Handler Exposure Data Sources and Assumptions
pages 21 - 33:**

Forestry: Although propargite is registered on Christmas trees and other ornamentals, there are currently no labeled uses for forestry plantations. Reference to forestry should be removed from these assessments and conclusions.

Almonds: The maximum use rate for almonds is 3.0 lb ai/acre, not 4.5 as listed.

Citrus: UCC currently does not support application of more than 3.15 lb ai/acre to citrus. References within the assessments to a maximum rate of 4.5 lb/acre should be changed and minimum MOEs recalculated accordingly.

Orchard Application: Application of propargite to tree crops at more than 2.1 lb ai/acre is atypical, but is sometimes necessary to control severe mite outbreaks in larger trees with full foliage. However, enclosed cabs are not common in some geographic regions of propargite use, and are a considerable investment. The option to use alternative PPE to provide an adequate MOE should be allowable in

such situations. Examples of such PPE include SMS or Tyvek® spraysuits, and/or gloves, headgear, and respiratory protection.

HED's Response: Forestry: Uniroyal is correct regarding no forest uses being registered. This error will be corrected in the revised risk assessment document.

Almonds: Tree nuts were assessed with a range of application rates with a maximum rate of 4.5 lb ai/acre for walnuts. The exposures were below HED's level of concern even at the maximum application rate of 4.5 lb ai/acre.

Citrus: Exposure was calculated for a range of application rates with a maximum application rate of 4.5 lb ai/acre based on the label for SLN CA860070. Exposures were below HED's level of concern even at 4.5 lb ai/acre.

Orchard Application: The issue regarding alternative PPE will need to have concurrence of the HED Exposure SAC.

Uniroyal's Comment:

Page 14: 4.3.2 Occupational Postapplication Exposure Scenarios

pages 34 - 56:

Citrus: (1) The maximum rate of 3.15 lb ai/acre should be assumed for citrus. (2) Additional DFR data should be used for post-application exposure assessment for citrus. Although several hazard assessment inputs have since changed, UCC recommends consideration of the OMITE®-CR citrus harvester assessment of 3/11/94 as fully inclusive of the best available information for citrus. Several appropriate DFR decline curves were used to quantify propargite decline in citrus, using the maximum rate of 3.15 lb ai/acre.

Grapes: Currently, CDPR has established a longer REI for "cane turning" in propargite- treated grapes than for "all other activities," following consensus that cane turning is the highest exposure activity in grapes. Since propargite-specific data on this activity indicate TCs ranging from approximately 2000 to 10200 cm²/hour, assessment of "cane turning" should utilize a TC no higher than 10200, and assessment of "all other activities" should utilize a lower TC. The resulting maximum REI should therefore be 27 days.

Tree Nuts: The Agency should consider requiring a separate and shorter REI specific to shaker harvesting. The TC for harvest (48 cm²/hour from the UCC shaker study) is markedly lower than that for "all other activities" and there is

occasionally a real agronomic need to be able to harvest close to the PHI for these crops. Moreover, use rates of more than 3.0 lb ai/acre are atypical and are not permitted in almonds. Therefore, for tree nut shaking, reentry at the PHI is more than adequately protective.

Mint: Parallel assessment of post-application exposure in mint and hops is not appropriate in view of the following:

- 1) The crop profiles of mint and hops are radically different. Hops grow well over 10 ft. high whereas mint is less than 3 ft.
- 2) Application to hops is usually by airblast whereas mint application is usually by boom, and with a different formulation type. Leaf surface characteristics are also different. Therefore, DFR data may not be transferable between the two crops.
- 3) Reentry activities in mint are almost non-existent. Mint is generally irrigated by overhead sprinkler and mechanically harvested. Hops has several points of reentry.

Therefore, placement of mint in virtually any other field crop category within this assessment would be more appropriate. Mint has far more in common with vegetable crops or oilseeds, for example, than with hops.

Hops: In view of the importance of propargite use as a miticide in hops, particularly as part of an IPM program, UCC is open to use of PPE for reentry into hops, in lieu of establishment of an REI that would preclude propargite use. Prior to consideration of such measures, assessment in the RED should include long-sleeved shirt and long pants as clothing protection since workers in hops-growing areas typically wear such clothing. The climate in these areas is cooler than in other propargite use areas.

HED's Response: Citrus: 1) Exposure was calculated for a range of application rates with a maximum application rate of 4.5 lb ai/acre based on the label for SLN CA860070. Exposures were below HED's level of concern even at 4.5 lb ai/acre.

2) HED used a Dislodgeable Foliar Residue study which had the best correlation for this scenario.

Grapes: The issue of using a lower TC will need to have concurrence of the HED Exposure SAC.

Tree Nuts: The issue of using a lower TC will need to have concurrence of the HED Exposure SAC.

Mint: HED will separate mint and hops and calculate separate exposures for the two crops.

Hops: The issue of replacing PPE in lieu of an extended REI will need to have concurrence of the HED Exposure SAC.

Uniroyal's Comment:

Page 15: 4.3.3 - Incident Information

page 57 - IDS incident #4066-12: Although grower records suggest that the 30 day REI was observed, DFR data taken by CDPR was aberrantly high, suggesting an excessive rate or a repeated application during the REI. Although CDPR (Worker Health & Safety Branch) substantially concurred with this interpretation, establishment of the same REI for cane turning as that for citrus harvesting was nevertheless considered to be appropriate. However, UCC and various researchers at CDPR would disagree with the statement, "it appeared that the label was followed".

HED's Response: The registrant notes there is a question about whether the incident involving 49 field workers in California involved compliance with the labeled re-entry interval. Other evidence suggests repeated application during the reentry interval and other researchers at the California Department of Pesticide Regulation believe the label may not have been followed. HED appreciates receiving this new information and believes that this incident should not be used as evidence that propargite can be responsible for illness after a reentry period of 30 days.

Uniroyal's Comment:

Page 15: 4.3.3 - Incident Information

page 58 - California data: Several of the incidents cited were also associated with use of sulfur. The low-cost plant nutritive and pesticidal properties of sulfur, and the resulting economic benefits, have made it the second most commonly used pesticide in California, second only to chlorine-based water treatment chemicals. Over the years, consulting dermatologists have concluded that such skin irritation is very difficult to definitively attribute to propargite vs. sulfur. As a result of this observation, the etiology of several of the incidents is in question.

HED's Response: The registrant notes that "several of the incidents cited were also associated with use of sulfur". This is not correct. The incident review does miss-state that "In 671 of these cases, propargite was used alone and was judged to be responsible for the health effects." Instead it should have said "In 671 of these cases, propargite was judged to be responsible for the health effects". California is well aware of the potential for sulfur to cause skin illness and as a result, 81 cases were excluded from further analysis because the cause of the illness could not be determined. However, in 7 cases where sulfur and propargite had been used together, careful study of usage

records and the exposure demonstrated that propargite was primarily responsible for the illness. Even if these 7 cases were excluded, it would not change the results of the analysis or the conclusions. From 1982 through 1996, propargite has been primarily responsible for 525 illnesses to the skin, more than any other pesticide including sulfur (which was responsible for 511). Other than the top 5 pesticides responsible for skin illness, propargite was responsible for at least 10 times as many cases as any other active ingredient.

Uniroyal's Comment:

Page 15: 5.0 Aggregate Risk Assessments and Risk Characterization

page 61 - The Uniroyal assessments include the risk from drinking water in the acute and chronic dietary exposure analyses. The analysis showed that for acute dietary exposure, the DWLOC for the three population subgroups examined exceeded by at least 35-fold the maximum value reported in the NAWQA water monitoring data. In the chronic dietary exposure analysis, average residues of propargite in drinking water based on the NAWQA data were 0.013 ppb, and that the risk contribution from drinking water was 2.76×10^{-8} (when zeroes were substituted for non-detects) to 5.13×10^{-8} (when half the LOD was substituted for non-detects). The aggregate exposure to potential propargite residues in both food and drinking water was 0.0000059 mg/kg bw/day, and is a negligible risk of 1.01×10^{-6} .

HED's Response: HED calculated the DWLOCs following the format in "OPP's Interim Approach for Addressing Drinking Water Exposure" (S. Johnson, 11/17/97).

Uniroyal's Comment:

Revised Propargite Quantitative Risk Assessment (Q_1^*) of 11/23/99

Page 16: The Agency obtained a revised Q_1^* of 2.01×10^{-1} , compared to the previous Q_1^* of 0.171. The revised value is in part based on the exclusion of animals that died before the first tumor. However, as noted in the attached memo from The K.S. Crump Group, and from a previously submitted memo (MRID No. 44213301), elimination of those animals that died before observation of the first tumor is not appropriate in a time-to-tumor model.

HED's Response: This issue has been addressed by HED in a previous memorandum (S. Shallal, 1/4/2000, D259592).

Uniroyal's Comment:

Anticipated Residues and Acute, Chronic, and Cancer Dietary Exposure and Risk Analyses for the HED Human Health Risk Assessment of 1/3/00

Page 17: Residue Information

Page 5 – Dry Beans

BEAD estimates of percent crop treated is 5% (ave.) and 10% (max.). Uniroyal estimates that the maximum percent crop treated is 2%.

Page 5 - Hops

BEAD estimates of percent crop treated are 56% (ave.) and 75% (max.). Uniroyal estimates are 5% and 8%, respectively.

Page 5 - Tea

For the acute and chronic analysis, BEAD makes the default assumption that 100% of tea is treated with Omite. Uniroyal estimates the figure to be approximately 0.3%.

Page 5 - Mint

For the acute and chronic analysis, BEAD assumes that 100% (default value) of the mint crop is treated. Uniroyal's estimates are 22% (ave.) and 34% (max.)

HED's Response: The Agency accepts these percent crop data and will incorporate them into the revised dietary exposure analysis which will be forthcoming.

Uniroyal's Comment:

Page 17: Residue Information

Page 6 – Grapes

The review for grapes cites an early processing study (MRID #40615501) which showed that propargite concentrated in raisins by a factor of 3.7x. A more recent grape processing study (MRID #43260801) was conducted which showed propargite concentration in raisins to be negligible (1.07x). In this study, which was not cited in the review, Omite treated grapes were field dried into raisin grapes and commercially cleaned and dried prior to packaging.

HED's Response: The Agency notes that Uniroyal in their calculation of the recent raisin processing factor (1.07x) did not use all four trials. It has been shown in market basket surveys that propargite concentrates in raisins. The Agency however will average the processing studies and use the average processing factor of 1.76x for calculation of the exposure from raisins.

Uniroyal's Comment:

**Page 17: Page 8 – Table 2,
Page 10 – Table 6**

Almond hulls are listed as comprising 10% of beef cattle diets. Data is available (Brooks, 1999) showing that almond hulls are fed almost exclusively to dairy cattle. The listing in these tables for percent dietary burden for almond hulls in beef cattle should be approximately zero.

HED's Response: HED accepts these comments and will calculate new dietary burdens for beef and dairy cattle.

Uniroyal's Comment:

Page 18 - 20: Comments pertaining to the HIARC document

- 1) Acute Dietary Endpoint for Females 13-50:
- 2) Multistage quantal model and revised Q_1^*
- 3) Acceptability of the mouse oncogenicity study.
- 4) Transient mitogenesis as a mode of action responsible for propargite carcinogenicity.

HED's Response: This issue has been addressed by HED in a previous memorandum (S. Shallal, 1/4/2000, D259592).

Uniroyal's Comment:

OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT of 2/10/00.

Page 23 1.2 Summary of Use Patterns and Formulations

page 9 - Registered Use Sites, Application Rates and Frequency of Application

The following corrections should be made to Table 4:

Specific Crop	Applic. Rate lb. ai/acre	Frequency of Application
Cherry, Nectarine, Prune	1.5 to 2.7	
Grapes	1.5 to 2.7	
Corn, Sorghum		1 except for 2 on Comite II corn SLN
Alfalfa, Clover		1
Peanut, Jojoba		2
Hops, Mints	1.5 – 2.3	
Ornamental Plants	Note: that Forest trees should be removed from listing).	

Some of the crops listed by EPA in Table 4 are non-bearing use only.

HED's Response: Cherry, nectarine, prune application rates range from 1.5 to 2.9 lb ai/acre. Table 4 in the Occupational and Residential Exposure Assessment will be revised specifying a range of application rates of 1.5 - 3 lb ai/acre. The maximum application rate is 2.9 lb ai/acre for grapes. This table entry will remain as it presently is stated in the Occupational and Residential Exposure Assessment. Table 4 in the Occupational and Residential Exposure Assessment will be revised to show 2 applications per year for corn. Frequency of application for alfalfa and clover is not specified on the labels, therefore, this entry in Table 4 will remain. The frequency of application for peanuts is indeed 2 per season. Table 4 in the Occupational and Residential Exposure Assessment will be revised to show 2 applications per year for peanut. The minimum application rate for hops and mint is 1.5 lb ai/acre. Table 4 in the Occupational and Residential Exposure Assessment will be revised to show an application rate range of 1.5 - 2.5 lb ai/acre for hops and mint. Forest planting will be removed from Table 4.

Uniroyal's Comment:

Page 23 1.2 Summary of Use Patterns and Formulations
page 9 - Registered Use Sites, Application Rates and Frequency of Application

Uniroyal wishes to bring to the Agency's attention the fact that proposed spray intervals for multiple treatments was included in a chart of current typical usage rates sent to EPA on 6/16/99. We did not find reference to these intervals in the draft RED chapters.

The minimum spray intervals provided to EPA by Uniroyal are:

Crop	Products	Min. Spray Intervals
Almonds	6E, 30W	21
Beans	Comite II	21
Christmas trees	6E, CR	28 (West) & 7 (East)
Citrus	Comite, CR	28
Corn, field	Comite II	42
Cotton	Comite II	21
Grapes	30W	21
Hops	6E, CR	21
Jojoba	Comite	21
Mint	Comite, 6E	21
Nectarines	30W	21
Peanuts	Comite, 30W	14
Potatoes	Comite, 6E	21
Roses	30W	14
Sugarbeets (seed)	Comite	21
Walnuts	6E, 30W	21
Non-bearing fruit & Nut	30W, CR	21
Non Bearings Nuts (in cotton & beans)	Comite	21
Non Bearing avocados	30W	21

HED's Response: These are minimum spray intervals proposed by Uniroyal and have not been considered by HED as of yet.

cc : Chem F, Chron F. Morton

RDI:Team (5/23/00); SVH:5/25/00

TM, Thurston Morton, Rm. 816D CM2, 305-6691, mail code 7509C